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Vinclozolin; CASRN 50471-44-8

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the [IRIS assessment development process](#). Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the [guidance documents located on the IRIS website](#).

STATUS OF DATA FOR Vinclozolin

File First On-Line 01/31/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	01/31/1987
Inhalation RfC (I.B.)	not evaluated	
Carcinogenicity Assessment (II.)	not evaluated	

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Vinclozolin

CASRN — 50471-44-8

Last Revised — 01/31/1987

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of

information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
Organ weight changes	NOEL: 100 ppm (2.5 mg/kg/day)	100	1	2.5E-2 mg/kg/day
6-Month Feeding Dog Study BASF Corp., 1982	LEL: 300 ppm (7.5 mg/kg/day)			

*Dose Conversion Factors & Assumptions: 1 ppm = 0.025 mg/kg/day (assumed dog food consumption)

I.A.2. Principal and Supporting Studies (Oral RfD)

BASF Wyandotte Corporation. 1982. MRID No. 00110446; HED Doc. No. 002214. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Vinclozolin was administered in the diet to 6 dogs/sex/group at levels of 0 (controls), 100, 300, 600, and 2000 ppm for 6 months. Toxic effects were noted at 300 ppm and consisted of significant increases in absolute and relative adrenal weights in male and females. This diagnosis was supported by the absolute and relative weight increases of the adrenals at 600 ppm and 2000 ppm and accompanied by histological findings. In females at 600 ppm and above there was vacuolation of the zona fasciculata and birefringence of the cortex in the adrenal. In males at 2000 ppm, the adrenal showed vacuolation of the zona fasciculata. In male dogs at 300 ppm and above, a decrease in absolute kidney weights was noted, and at 600 ppm and above the kidneys showed fat droplets in the distal tubules.

I.A.3. Uncertainty and Modifying Factors (Oral RfD)

UF — An uncertainty factor of 100 was used to account for the inter- and intraspecies differences. The 6-month dog study is of marginal duration to qualify as a long-term study. An additional UF of 10 to account for the lack of a "chronic" dog study (at least 1 year) was not considered necessary, since 1) the other toxicologic studies on vinclozolin generally did not

indicate that the toxicologic endpoints would be seen at lower doses with extended exposure, 2) the effects seen at the LEL in the 6-month dog study are of a minor toxicologic nature, and 3) the dog is the most sensitive species tested by far.

MF — None

I.A.4. Additional Studies/Comments (Oral RfD)

Data Considered for Establishing the RfD

- 1) 6-Month Feeding - dog: Principal study - see discussion above; core grade minimum
- 2) 103-Week Feeding (Oncogenic) - rat: Systemic NOEL=486 ppm (24.3 mg/kg/day), Systemic LEL=1458 ppm (72.9 mg/kg/day) (body weight reduction, reduced serum bilirubin); no core grade (BASF Wyandotte Corp., 1977a)
- 3) 3-Generation Reproduction - rat: NOEL=1458 ppm (72.9 mg/kg/day) (HDT); Teratogenic NOEL=1458 ppm (HDT); no core grade (BASF Wyandotte Corp., 1977b)
- 4) Teratology - rabbit: NOEL=300 mg/kg/day (HDT); Fetotoxic NOEL=80 mg/kg/day; Teratogenic NOEL=300 mg/kg/day (HDT); core grade minimum (BASF Wyandotte Corp., 1981)
- 5) Teratology - mice: Teratogenic NOEL=6000 ppm (900 mg/kg/day); Fetotoxic LEL=6000 ppm (resorptions); no core grade (BASF Wyandotte Corp., 1975)

Other Data Reviewed

- 1) 26-Month Feeding (Oncogenic) - mouse: Systemic NOEL=486 ppm (72.9 mg/kg/day); Systemic LEL=1458 ppm (7219 mg/kg/day) (decrease body weight gain in males); core grade minimum (BASF Wyandotte Corp., 1977)

Data Gap(s): None

I.A.5. Confidence in the Oral RfD

Study — High
Database — High
RfD — High

The critical study is of high quality and is given a high confidence rating. The other studies are also of good quality; thus, the database is given a high confidence rating. High confidence in the RfD follows.

I.A.6. EPA Documentation and Review of the Oral RfD

Pesticide Registration Files

Agency Work Group Review — 07/08/1986

Verification Date — 07/08/1986

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for Vinclozolin conducted in September 2002 identified one or more significant new studies. IRIS users may request the references for those studies from the IRIS Hotline at hotline.iris@epa.gov or (202)566-1676.

I.A.7. EPA Contacts (Oral RfD)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Vinclozolin

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Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Vinclozolin

CASRN — 50471-44-8

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

III. [reserved]

IV. [reserved]

V. [reserved]

VI. Bibliography

Substance Name — Vinclozolin
CASRN — 50471-44-8

VI.A. Oral RfD References

BASF Wyandotte Corporation. 1975. MRID No. 00062644; HED Doc. No. 000244. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

BASF Wyandotte Corporation. 1977a. MRID No. 00070036; HED Doc. No. 000244. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

BASF Wyandotte Corporation. 1977b. MRID No. 00062645; HED Doc. No. 000244. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

BASF Wyandotte Corporation. 1977c. MRID No. 00070037; HED Doc. No. 000244, 001885, 002717, 002669. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

BASF Wyandotte Corporation. 1981. MRID No. 00085079; HED Doc. No. 002409. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

BASF Wyandotte Corporation. 1982. MRID No. 00110446; HED Doc. No. 002214. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Vinclozolin

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Date	Section	Description
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.

VIII. Synonyms

Substance Name — Vinclozolin

CASRN — 50471-44-8

Last Revised — 01/31/1987

- 50471-44-8
- BAS 35202F
- BAS 35204
- BAS352-04F
- Ronilan
- Vinclozolin